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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,770	05/24/2007	Gloria Astrid Limb	GJE.1057	7263
23557 7590 04/01/2010 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER SCHUBERG, LAURA J				
ART UNIT 1657		PAPER NUMBER		
NOTIFICATION DATE 04/01/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

### Office Action Summary

**Application No.**

10/580,770

**Applicant(s)**

LIMB ET AL.

**Examiner**

LAURA SCHUBERG

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 9/27/07 9/15/09

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-7) in the reply filed on 12/28/2009 is acknowledged. The traversal is on the ground(s) that since Applicant has canceled claims 14 and 15 the unifying technical feature that the remaining inventions now have is de-differentiating of Muller cells. Applicant asserts that since the Isseroff et al reference does not describe the de-differentiation of Muller cells that Inventions I and II must share a special technical feature not known in the prior art. This is not found persuasive because the de-differentiation of Muller cells is known in the prior art as well as described by Fischer et al (Glia, published online May 2003). The expression "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13 are pending. Claims 14-15 were newly canceled and no claims have been amended.

Claims 8-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-7 have been examined on their merits.

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: pictures A and B. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claims 2 and 5 objected to because of the following informalities: The growth factors (EGF, FGF and TGF) should be spelled out at their first appearance in the claims for purposes of clarity.

There should also be a comma between FGF-2 and retinoic acid as they are two different agents.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al (Glia, published online May, 2003).**

Claim 6 is drawn to a composition comprising dedifferentiated Muller cells obtainable by a method comprising culturing Muller cells in the presence of an extracellular matrix protein and a growth factor to thereby induce dedifferentiation of the Muller cells into progenitor phenotype.

This claim is a product-by-process claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes

put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Fischer et al teach a method of de-differentiating Muller cells from chickens in the presence of growth factors (page 73). While Fischer et al are silent with regard to the presence of extracellular matrix proteins during the process; it appears as though the de-differentiated Muller cells produced would be structurally the same. Evidence provided demonstrating a structural difference between the de-differentiated Muller cells might be able to overcome this rejection.

Therefore the teaching of Fischer et al anticipates Applicant's invention as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keating et al (US 2004/0087016) in view of Fischer et al (Glia, published online May 2003).**

The claims are drawn to a method for the production of retinal cells comprising obtaining Muller cells; culturing the Muller cells in the presence of an extracellular matrix protein and a growth factor to thereby induce dedifferentiation of the Muller cells into progenitor phenotype and composition produced. Dependent claims include wherein the Muller cells are human and wherein the method further comprises culturing the dedifferentiated cells in the presence of an extracellular matrix protein and a differentiation agent to induce the dedifferentiated cells to adopt a specific differentiated cell phenotype.

Keating et al teach a method of using dedifferentiating agents to dedifferentiate cells to produce a progenitor cell phenotype and then use differentiating agents to re-



differentiate the de-differentiated cells into a specific desired differentiated phenotype such as a neuron or glial cell (page 2 paragraphs 22-24 and page 5 paragraphs 46-47). Human cells are suggested as desirable (page 1, paragraph 3 and 8 and page 5 paragraph 53). The culture conditions include media that has been supplemented with growth factors such as bFGF (FGF-2), EGF, IGF or insulin and substrates that include laminin, collagen and fibronectin (page 45 paragraph 424). A skilled artisan is taught to know how to vary the conditions set forth to achieve dedifferentiation and differentiation (page 45 paragraphs 429-431). Medical conditions for which the cells produced could be used for include eye-related degeneration such as for the retina (page 7 paragraph 68).

Keating et al do not specify that Muller cells are to be used for dedifferentiating.

Fischer et al teach that Muller cells can be dedifferentiated by exposing them to dedifferentiating agents (pages 73). Fischer et al suggest that these dedifferentiated Muller cells may have the potential to generate all retinal cell types (page 71, column 2). FGFs, insulin and insulin-like growth factor are suggested as growth factors to use in dedifferentiating the Muller cells (page 73, column 1).

Therefore it would have been obvious to use the Muller cells in the dedifferentiating/re-differentiating method of Keating et al. One of ordinary skill in the art would have been motivated to do so because Fischer et al teach that de-differentiated Muller cells may have the potential to generate retinal cell types and Keating et al teaches that the use of de-differentiated cells for the treatment of retinal degeneration is desired. One of ordinary skill in the art would have been motivated to modify the culture

conditions to include those growth factors and extracellular matrix proteins that would allow the Muller cells to dedifferentiate and redifferentiate in the greatest number as fast as possible (result effective variables). One of ordinary skill in the art would have had a reasonable expectation of success because Fischer teach that Muller cells can be dedifferentiated by modifying the culture conditions and Keating et al teaches that the cells used can be taken from the injured patient and manipulated to produce neurons or glial cells (page 5 paragraph 47 and page 9 paragraph 89).

Therefore the combined teachings of Keating et al and Fischer et al render obvious Applicant's invention as claimed.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Schuberg  
Examiner  
Art Unit 1657

/Laura Schuberg/